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| 10/645,405 | 08/21/2003 | Stanley B. Pollak | 1656-2 | 7777 |

7590 03/15/2007
Galgano & Burke
Suite 35
300 Rabro Drive
Hauppauge, NY 11788

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| EXAMINER |
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NGUYEN, TUAN VAN

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| ART UNIT | PAPER NUMBER |
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3731

| SHORTENED STATUTORY PERIOD OF RESPONSE | MAIL DATE | DELIVERY MODE |
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Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

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|------------------------------|--------------------------------------|--------------------------------------|--|
| Office Action Summary | Application No. 10/645,405 | Applicant(s) POLLAK ET AL. | |
| | Examiner Tuan V. Nguyen | Art Unit 3731 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 August 2003 and 27 September 2004.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-22 is/are pending in the application.
4a) Of the above claim(s) 10-14 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-9 and 15-22 is/are rejected.
- 7) ☒ Claim(s) 3 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 21 August 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date <u>8/21/03</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restriction

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
 - I. Claims 1-9 and 15-22, drawn to an apparatus for closing a wound, classified in class 606, subclass 144.
 - II. Claims 10-14, drawn to method of closing a wound, classified in class 128, subclass 898.

The inventions are distinct, each from the other because of the following reasons:

Inventions II and I are related as process and apparatus for its practice. The inventions are distinct if it can be shown that either: (1) the process as claimed can be practiced by another materially different apparatus or by hand, or (2) the apparatus as claimed can be used to practice another and materially different process. (MPEP § 806.05(e)). In this case the process as claimed can be practiced by another and materially different apparatus that does not have a obturator.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least

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one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

2. A telephone call was made to Mr. Thomas Galgano (Reg. No. 27,638) on December 19, 2006 to discuss the above restriction requirement. The result was a provisional election was made with traverse to prosecute the invention of Group I, claims 1-9 and 15-22. Affirmation of this election must be made by applicant in replying to this Office action. Claims 10-14 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claim 3 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claim 3, lines 2, recites limitation "a needle mounting plate secured to said skin pressure plate" and lines 5-7 recites limitation "said rotatable locking nut is threadably received on said split collar of

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said needle mounting plate and, upon tightening, locks said needle mounting plate and, in turn, said skin pressure plate to said central shaft. Turning to specification Fig. 1 for guidance, one found in page 8, first full paragraph, line 8 described "the needle mounting plate 26 which is movable over the central shaft" and second full paragraph, lines 3-10, described "the skin pressure plate 16 has a central bore 17 and is preferably coupled to the central shaft via knurled locking nut 44 threadably received on a threaded split collar 46 centrally mounted on skin pressure plate 16 about central bore 17 and mounted on central shaft 14. locking nut 44 tightens the split collar 46 against shaft 14 thereby fixing the skin pressure plate 16 to central shaft 14". Examiner suggests applicant change claim 3 to read:

An apparatus according to claim 2, further comprising:

g) a needle mounting plate [[secured to said skin pressure plate having a threaded split collar coaxially disposed on said central shaft]] mounted to said central shaft; and

h) said skin pressure plate having a threaded split collar coaxially disposed on said central shaft and a rotatable locking nut, wherein said rotatable locking nut is threadably received on said split collar of said [[needle mounting]] skin pressure plate and, upon tightening, locks said [[needle mounting plate]] skin pressure plate to said central shaft.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:
 1. Determining the scope and contents of the prior art.
 2. Ascertaining the differences between the prior art and the claims at issue.
 3. Resolving the level of ordinary skill in the pertinent art.
 4. Considering objective evidence present in the application indicating obviousness or nonobviousness.
7. **Claims 1, 4, 5, 15 and 17-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Levinson (U.S. 6,245,080) in view of Stevens (U.S. 5,722,981).**
8. Referring to claims 1, 4, 5, 15 and 17-19, Levinson discloses (see Figs 23C-24C) a apparatus for applying a suture to a wound, comprising: an obturator 240a, 240, 242 at the distal end of shaft 224b wherein the obturator has a bulbous distal end 242 a pair of fins, which is the taper portion connecting 242 with 240, fascia supporting shelf 240a; a pair of suture needle 230, 232, each of said needles having a sharp end and being movable from a first position where said sharp ends are distant from said obturator 240 to a second position where said sharp ends are closes to said obturator 240 (see Fig. 24C); a suture control mechanism (see Fig. 23C) coupled to one of said needles for delivery suture material through the sharp

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end of the needles. Levinson discloses the invention substantially as claimed except for a snare control mechanism coupled to the other of said needles for delivering a snare through the sharp end of the needle.

9. Still referring to claims 1, 4, 5, 15 and 17-19, however, Stevens discloses (see Figs. 7a-7c) a double needle ligature device for closing of trocar wound (see Abstract) comprising: two hollow needles, a suture control mechanism 116, 118 coupled to one of said needles for delivery suture material 121' through the sharp end of the needles, and a snare control mechanism 116, 118 coupled to the other of said needles for delivering a snare through the sharp end of the needle (see col. 5, lines 30 to col. 6, line 10). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made by the applicant to incorporate the two hollow needles with control mechanism to delivery suture and snare for capturing of the suture and furthermore, the device of Levinson can be modified in view of Stevens to have two sharp ends of said needles pass through the obturator 240a, 240, 242 for the purpose of closing a laparoscopic wound, as disclosed by Stevens, to incorporate into the device, as disclosed by Levinson in order to gain the advantages of minimizes the chance of inadvertently losing hold of the suture during needle withdrawal as suggested by Levinson (see col. 1, lines 48-51).
10. **Claims 2, 7-9, 16 and 20-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Levinson (U.S. 6,245,080) in view of Stevens (U.S. 5,722,981) further in view of Hasson (U.S. 5,984,948).**

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11. Referring to claims 2, 7-9, 16 and 20-22, the modified device of Levinson discloses the invention substantially as claimed except for a plate mounted on said shaft and movable relative said obturator.
12. Still referring to claims 2, 7-9, 16 and 20-22, Hasson discloses (see Fig. 1) a device for closing an opening in tissue comprising: a shaft 22, among other things, a sealing member 18, wherein sealing member having taper 32 that capable of stretching tissue, mounted on said shaft and movable relative to balloon 103 (see col. 5, lines 12-37). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made by the applicant to incorporate the sealing member and sealing surface that capable of movable relative to the shaft, as disclosed by Hasson, to incorporate into distal end surface of needle retention body 234 of the modified device, as disclosed by Levinson in order to gain the advantages of performing a full thickness closure because the incision is sealed by the sealing surface 32, thus the leakage of gas out of peritoneum is minimize therefore allow the surgeon to perform full thickness closure as suggested by Hasson (see col. 1, lines 55-60).

Allowable Subject Matter

13. Claim 3 would be allowable if rewritten as suggested by the examiner in paragraph 4 to overcome 35 U.S.C. § 112 rejection and in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Tuan V. Nguyen whose telephone number is 571-272-5962. The examiner can normally be reached on M-F: 9:00 AM - 5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, AnhTuan Nguyen can be reached on 571-272-4963. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Tuan V. Nguyen
December 18, 2006


ANH TUAN T. NGUYEN
SUPERVISORY PATENT EXAMINER *(GPR)*